DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 11, 2015

Medtronic, Inc.
Mia Hunt
Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K143316
Trade/Device Name: Attain Hybrid Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 4, 2015
Received: February 5, 2015

Dear Mia Hunt,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K143316
Device Name: Attain Hybrid Guide Wire
Indications for Use: The Attain Hybrid guide wire is intended to aid in the placement of Medtronic transvenous left ventricular leads in the coronary vasculature.

Prescription Use _X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary K143316

[As required by 21 CFR 807.92]

Date Prepared: March 4, 2015

Submitter: Medtronic, Inc.
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General Information

Trade Name: Attain Hybrid Guide Wire

Common Name: Catheter Guide Wire

Regulation Number: 21 CFR 870.1330

Product Code: DQX

Classification: Class II

Classification Panel: Cardiovascular

Special Controls: Not applicable

Predicate Devices: Attain Hybrid Guide Wires K063210

Device Description

A guide wire is a flexible wire of a small diameter that serves as a track for directing or passing a device to a vessel, organ or cavity, by threading the device over its length.

Indications for Use

The Attain Hybrid Guide Wire is intended to aid in the placement of Medtronic transvenous left ventricular leads in the coronary vasculature.

Technological Characteristics

When compared to the predicate device (K063210), the modified Attain Hybrid Guide Wires presented in this submission have the same:

- Intended use/indications for use
- Operating principle
- Basic design features
- Device functionality
- Biological safety
- Packaging materials
- Sterilization and sterility assurance level
- Shelf life

The modified Attain Hybrid Guide Wires and the predicate device differ in the following:

- PTFE formulation
- Tip and distal segment stiffness

Substantial Equivalence and Summary of Studies:

Technological differences between the subject and predicate devices have been evaluated through bench tests to provide evidence of safe and effective use. Modified Attain Hybrid Guide Wires are substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design and materials have been verified through the following tests:

- Bench/performance tests:
    - Coating adhesion
    - Dimensional verification
    - Particulate PTFE coating adhesion test (Coating Integrity)
    - Tip integrity
    - Tip deflection force
    - Distal tip stiffness
    - Guide Wire Perforation
    - Guide Wire Passage/Seal Integrity
    - Silicone lubricity and durability

    - Guide wire torque response
- Sterilization validation
- Shelf life evaluation
- Biocompatibility tests per ISO 10993-1:
    - Cytotoxicity
    - Irritation or Intracutaneous Reactivity
    - Systemic Toxicity
    - Hemocompatibility / Hematology
    - Hemocompatibility / Thrombosis
    - Pyrogen Test
    - Complement Activation Assay
    - Sensitization Test

Conclusion:

The results of the above verification tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the modifications made to the Attain Hybrid Guide Wires described in this submission result in a device that is substantially equivalent to the predicate.